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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,224	06/05/2001	Geert Maertens	2752-45	4458

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

MARTINELL, JAMES

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,224

Applicant(s)

MAERTENS ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/5/01 & 8/25/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/27/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Majzoub et al (Proc. Natl. Acad. Sci. USA. 258: 14061 (1983)) listed on PTOL-1449 filed June 27, 2005 is crossed out because the reference is already of record (see the PTOL-1449 filed August 25, 2003).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed May 18, 2005, paragraph bridging pages 2-3). Applicants' arguments (response filed June 27, 2005, pages 13-14) are not convincing because applicants do not address the merits of the rejection of the instant claims.

Claims 24-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed May 18, 2005, pages 3-5). Applicants' arguments (response filed June 27, 2005, pages 14-19) are not convincing. The instant application does not teach one of skill in the art how to make and use oligonucleotide probes or primers with the claimed properties of specificity of hybridization in view of (the Office action mailed May 18, 2005 at page 3, lines 13-14 incorrectly stated "resulting from" instead of "in view of") the sequences that the various HCV types and subtypes have in common as is evidenced by the Figures in the application. Sequences shared by different types and subtypes of HCV would cross-hybridize to oligonucleotide probes, thus making such probes non-specific for a given type or subtype of HCV. Applicants' arguments in connection with Kennell (response filed June 27, 2005, pages 15-16) are most unconvincing. The examiner did not suggest that an upper limit of

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50 nucleotides be included in the claimed fragments. In addition, applicants' reading of Kennell is too narrow. Applicants do not point to any passage of Kennell that suggests that the teaching in Kennell (*e.g.*, paragraph bridging pages 260-261) should be limited to be "only instructive with regard to Kennell's fragment". This interpretation is inexplicable in view of the fact that Kennell discusses thermal stability of double stranded nucleic acid hybrids based upon the G+C content of the nucleic acids involved. This is clearly a general teaching and not limited to any particular fragments. Applicants' argument (page 16) in connection with mismatches is unconvincing because applicants' arguments disregard the lower end of the range recited in Kennell as being important in reaching the point of maximum stability of a duplex (*i.e.* the range of 25-50 nucleotides). Thus, a run of 25 nucleotides of high G+C content would, according to Kennell, reach maximum stability, so that one or a few nucleotides mismatch in other regions of a probe would not change the binding properties of the probe relative to any putative target nucleic acids. Applicants' argument in connection with what one of skill in the art would do to design a specific probe with the claimed properties (paragraph bridging pages 16-17) is not convincing because one would need to know which parts of the HCV genome referred to in the claim are unique to HCV 3c nucleotides 1-346 of the core region. This is what is not disclosed in the instant application. The reasons for this rejection based upon Wallace et al (Methods Enzymol. 152: 432 (1987)) stand for reasons already of record. The part of this rejection based upon a lack of a teaching of DNA amplification using only one primer is withdrawn. The reference to "no prior art of record" in the rejection (*e.g.*, Office action mailed May 18, 2005, page 5) is intended to refer only to prior art predictive of HCV 3c subtype-specific oligonucleotide probes and not to any prior art in general that may have been cited in the instant application. Finally, in regard to the number of possible oligonucleotide probes, it is noted that the claims prior to the amendment filed June 27, 2005 were drawn to probes specific for HCV 3c. The genome of HCV 3c is over 9000 nucleotides in length. Therefore, there are about 387,000 probes of 8-50 nucleotides length that can be made from 9000 nucleotides. The claims as amended June 27, 2005 are drawn to probes from a more limited region of the HCV 3c genome of 346 nucleotides. There are 13,674 probes of 8-50 nucleotides length that can be made from 346 nucleotides. While

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13,674 may not be an astronomical number, it is still large enough such that without guidance as to which oligonucleotides are or may be unique to HCV 3c and given the empirical nature of discovering which are, it would require undue experimentation for one of ordinary skill in the art to practice the full scope of the claimed invention.

Claims 24-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The application does not provide an adequate written description of the claimed invention because no probes with the desired properties are described. The discussion in the rejection immediately above is incorporated here.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. Only documents such as those intended for use in a personal or telephone interview should be faxed to the examiner's desktop workstation. Any Official Communication to the USPTO should be faxed to (571) 273-8300.

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The examiner works a flexible schedule and can be reached by phone and voice mail.

Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.


OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
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9/16/05